

**REMARKS**

Entry of the foregoing and further and favorable consideration of the subject application are respectfully requested and such action is earnestly solicited.

The Office Action incorrectly states the status of the claims in the present application. While Applicant agrees that Claims 1, 3-7, 9-12, and 14-24 are pending in the present application, Applicant disagrees with the Examiner's listing of the claims withdrawn from consideration. The Examiner states that Claims 6, 7, 9-12, 14-21, 23, and 24 stand withdrawn from consideration as drawn to a non-elected invention. However, Applicant respectfully submits that Claims 16 and 21 should still be under consideration as they are drawn to a composition, rather than methods of treating obesity or maintaining a desired body weight. Claim 21 is canceled by the present amendment, thereby mooting the issue for this claim. However, Applicant respectfully submits that Claim 16 should be listed as still under consideration.

By the present amendment, Claims 4, 6, 7, 9-12, 14, 15, and 17-24 have been canceled, without prejudice to or disclaimer of the subject matter contained therein. Applicant expressly reserves the right to file a continuation or divisional application on any canceled subject matter.

By the present amendment, Claims 1, 3, 5, and 16 have been amended to more clearly define the invention and to recite the synergistic thermogenic qualities of the presently claimed invention. Support for these amendments can be found in the *in vitro*, *ex vivo*, and *in vivo* studies found on page 7, line 14, to page 9, line 29. Additionally, Claim

1 has been amended to incorporate the subject matter of Claim 4. Accordingly, no new matter has been added.

By the present amendment, new Claims 25-28 have been added. New Claim 25 derives support from, at least, original Claim 1 and the specification on page 10, lines 6-16. New Claims 26-28 derive support, at least, from that cited above for Claim 25 and Claims 3, 5, and 16, respectively. Accordingly, no new matter has been added.

#### *Interview Summary*

Applicant gratefully acknowledges the courtesy shown to the Applicant's undersigned representative, Jennifer Topmiller, by Examiner Patten on October 2, 2002. During the interview, Examiner Patten maintained her position that the present claims were obvious over the cited Kimura *et al.* patent. Examiner Patten also noted that green tea is *Camellia sinensis* and is commonly known by the skilled artisan. Examiner Patten further indicated that Kimura did not teach an 80% alcohol extract but that such a claim amendment would require further search and/or consideration.

#### *Rejections Under 35 U.S.C. § 103*

Claims 1, 3-5, and 22 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Kimura *et al.* (U.S. Patent No. 5,776,756). The Examiner maintains this rejection alleging that the claims do not contain any mention of a specific species of green tea or a particular extraction method. The Examiner asserts that because Kimura suggests the use of ethanol as an extraction solvent that a green tea extracted by this method would

inherently possess the claimed extract characteristics. Moreover, during the October 2, 2002 interview, Examiner Patten asserted that *Camellia sinensis* is a common green tea.

Initially, Applicant note that if Claim 16 had been considered (see note above regarding claims withdrawn from consideration), the following remarks are equally applicable to this claim, should the Examiner deem it to fall within this rejection.

Claim 22 has been canceled by the present amendment, thereby mooting this rejection as it applies to this claims. This rejection, as it applies to Claims 1 and 3-5 and as it may apply to Claim 16 and new Claims 25-28, is respectfully traversed.

In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See* M.P.E.P. §2142.

Applicant respectfully submits that Kimura *et al.* do not provide any motivation to produce a green tea extract of the present invention. First, Kimura *et al.* merely mention green tea extract as a minor ingredient in a composition possessing superoxide dismutase (SOD) activity. Kimura *et al.* certainly do not identify any active ingredients in green tea motivating the inclusion of the extract in the overall SOD composition. Accordingly, one would not have been motivated to produce a green tea extract with the particular combination and amounts of catechols and caffeine of the presently claimed invention, except in hindsight based on Applicant's disclosure. Applicant further notes that even if Kimura *et al.* had described a particular active component to be optimized in the green tea

extract, one skilled in the art would still not arrive at the present invention which optimizes catechols and caffeine for the purpose of a synergistic thermogenic effect.

Moreover, Kimura *et al.* disclose that the "concentration of the extracted component should preferably be in the range of approximately from 5 to 50 wt%." Col. 4, lines 36-38. Kimura *et al.* note that if "the amount exceeds 50 parts by weight, it can become difficult to take it as a drink..." Col. 4, lines 43-45. In Col. 5, lines 60-64, Kimura give an example of an ethanol or water extract which has "a solid content of 47 to 48% and a concentration of ethanol and glycerin (mainly composed of ethanol) of about 50 wt % with a water content of about 2.6% and a specific gravity of 1.07 to 1.09." Given the high concentration of catechols and caffeine of the presently claimed invention, it is unlikely that these preferred embodiments of Kimura *et al.* would possess the characteristics of the claimed invention as the extract would not be concentrated enough. Thus, not only does Kimura *et al.* not provide motivation to arrive at the green tea extract of the presently claimed invention, Kimura *et al.* also teach away from the presently claimed invention.

Applicant respectfully submits that Kimura *et al.* does not disclose a green tea extract possessing between 20%-50% catechols and 5-10% caffeine. Nor does Kimura *et al.* disclose the use of an 80% ethanol extraction. Thus, Kimura *et al.* does not disclose or suggest all of the claim limitations. The Examiner acknowledges the deficiency of Kimura *et al.* in describing the particular catechol and caffeine content of the claimed invention, but merely argues that such a concentration would be inherent in the green tea extract of Kimura *et al.*

The Examiner has previously noted that a *prima facie* case of obviousness can be rebutted by a showing that the prior art products do not necessarily possess the characteristics of the claimed product. Office Action mailed November 2, 2001 (Paper No. 12), page 6, citing *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). Assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness, Applicant respectfully submits that evidence that the green tea extract of Kimura *et al.* does not necessarily possess the characteristics of the claimed invention was previously submitted to the Examiner in the Reply and Amendment filed April 2, 2002.

Applicant points out that all teas (black, green, and oolong) derive from the *Camellia sinensis* plant. However, there are at least hundreds of different varieties of these three types of tea. Accordingly, simply because Kimura *et al.* generically mention a "green tea extract," one skilled in the art would not be led to believe that the green tea extract would have the same characteristics as those claimed. In fact, as noted above, based on the preferred embodiments described by Kimura *et al.*, Applicant submits that one skilled in the art would be led to the opposite conclusion.

In the April 2, 2002 Reply, Applicant presented evidence that the choice of green tea variety and extraction solvent play a significant role in arriving at a green tea extract of the presently claimed invention. Specifically, on page 7 of the April 2, 2002 Reply, Applicant demonstrated that out of several types of tea extracted with 80% ethanol, only Assamica type met the particular requirements of the presently claimed invention. Additionally, on page 8 of the April 2, 2002 Reply, Applicant showed that varying the concentration of ethanol used in the extraction profoundly impacts the catechol and caffeine

concentration of the extract. Applicants express their willingness to incorporate this data into an expert declaration should the Examiner deem necessary.

A case of *prima facie* obviousness based on overlapping ranges can be rebutted by showing the criticality of the claimed range. Importantly, the present specification shows the criticality of the claimed range and ratio in providing the synergistic thermogenic effects of the claimed invention. Accordingly, even assuming *arguendo* that Kimura *et al.* may inherently teach a range of these particular constituents by failing to state either tea type or extraction solvent, there is no motivation in Kimura *et al.* to arrive at the specific concentrations and/or ratio of catechols and caffeine in the presently claimed invention.

Thus, there are gaping holes in the disclosure of Kimura *et al.* that the Examiner has not provided any supplementary evidence to fill. First, Kimura does not specify the starting tea type for the extract. Second, Kimura *et al.* do not suggest the desirability of a particular extraction solvent. Third, Kimura *et al.* do not describe any particular characteristics of the green tea extract, other than desired weight percents of solids, which teach away from the present invention. Fourth, Kimura *et al.* does not disclose nor suggest that a particular concentration or ratio of caffeine and catechols would be desirable such that one skilled in the art would be led to the present invention, even if for a different purpose.

Applicant further submits that the recitation of a specific tea variety and an extraction solvent in the presently claimed invention are unnecessary as it is the identification by the Applicant of a particular combination of the catechols and caffeine in a particular concentration and ratio of the presently claimed invention that is the salient

feature. Accordingly, Applicant should not be limited to a particular tea variety or extraction method as the disclosure of the present application provides the motivation for one skilled in the art to other possible varieties of tea and extraction methods to obtain the beneficial composition of the presently claimed invention. Moreover, the specification and the knowledge in the art provide the skilled artisan with the capacity to readily identify such extracts using routine chemical analysis.

Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness has not been established. Furthermore, even if the Examiner maintains that such a case has been made out, Applicant respectfully submits that sufficient evidence to rebut such a case has been submitted. Withdrawal of this rejection is respectfully requested.

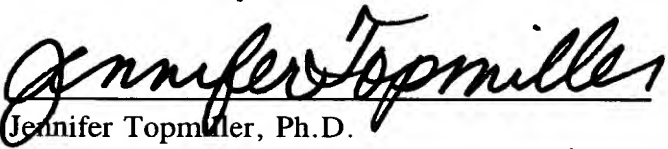
*Conclusions*

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:   
Jennifer Topmiller, Ph.D.  
Registration No. 50,435

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: October 15, 2002



**Attachment to REPLY & AMENDMENT dated October 15, 2002**

**Marked-up Claims 1, 3, 5, and 16**

1. (Four Times Amended) [A composition] An extract of green tea for the curative and prophylactic treatment of obesity, comprising [an extract of green tea wherein said extract contains] from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine, said catechols and caffeine being present in said extract in a combined synergistic thermogenically effective amount, the ratio of the concentration of catechols to the concentration of caffeine in said extract being between 2 and 10.

3. (Three Times Amended) [A composition] An extract of green tea according to Claim 1, [wherein the extract of green tea contains] comprising from 20% to 30% by mass of catechols expressed as epigallocatechol gallate (EGCG).

5. (Three Times Amended) [A composition] An extract of green tea according to Claim 1, [wherein the extract of green tea is titrated so that a daily dose of the composition contains] comprising from 250 mg to 500 mg of catechols, and from 50 mg to 200 mg of caffeine, per daily dose.

16. (Three Times Amended) [A composition] An extract of green tea according to Claim 5, [wherein said daily dose of the composition comprises] comprising about 375 mg of catechols and about 150 mg of caffeine.